FDA U.S. FOOD & DRUG ADMINISTRATION

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Overview Of The MDSAP Audit Process

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Learning Objectives

- List the prerequisites for a Medical Device Single Audit Program (MDSAP) Auditor
- Describe the MDSAP Audit process and provide examples
- Review requirements for writing nonconformity statements and the final report

Learning Objectives

- **List the prerequisites for an MDSAP Auditor**
- Describe the MDSAP Audit process and provide examples
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MDSAP Auditor Prerequisites

MDSAP Auditor is expected to:

-Be affiliated with an MDSAP recognized auditing organization or

- Be employed by one of the MDSAP participating regulatory authorities

- Be proficient in auditing to the International Organization for Standardization (ISO) 13485: 2016 standard

- Be familiar with the specific requirements of participating regulatory authorities

- Successfully complete the MDSAP training program

Learning Objectives

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- **Describe the MDSAP Audit process and provide examples**
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MDSAP Audit Process

- Each MDSAP Audit process contains:
  - A purpose
  - A number of anticipated outcomes or objectives that are further broken down into specific tasks
- The audit tasks are based on the clauses in ISO 13485:2016 and the regulatory requirements of the participating Regulatory Authorities
- Each task has audit criteria associated with it

MDSAP Audit Process

- It is expected that the auditor is proficient in auditing to ISO 13485:2016 and is familiar with specific requirements of:
  - Australia's Therapeutic Goods Administration,
  - Brazil’s ANVISA,
  - Health Canada
  - Japan’s MHLW
  - United States’ Food and Drug Administration

MDSAP Audit Process

- Australia requirements
  - Therapeutic Goods Act 1989
  - Therapeutic Goods (Medical Devices) Regulations 2002
  - Uniform Recall Procedure for Therapeutic Goods (URPTG)
- Brazilian Medical Device Regulation
  - Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013)

MDSAP Audit Process

- Health Canada requirements
  - Medical Device Regulations (SOR/98-282)
- Japan requirements
  - Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169)

MDSAP Audit Process

- United Sates Food and Drug Administration requirements
  - Labeling (21 CFR 801)
  - Quality System Regulation (21 CFR 820)
  - Medical Device Reporting (21 CFR 803)
  - Medical Devices: Reports of Corrections and Removals (21 CFR 806)
  - Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices (21 CFR 807)
  - Medical Device Tracking Requirements (21 CFR 821)
  - Unique Device Identification (21 CFR 830)

MDSAP Audit Process

- Audit Tasks
  - The auditor assesses the organization's conformity to the applicable clause of ISO 13485:2016
  - The auditor assesses any additional country-specific requirement
  - Incorporate the requirements of the applicable ISO 13485:2016 clause and aspects of country-specific requirements

MDSAP Audit Process

- Why not just perform an audit to ISO 13385:2016?
  - Not all of the regulatory authorities have adopted ISO 13485:2016 as their regulatory requirement
  - There are additional requirements contained in Brazilian Good Manufacturing Practices (RDC ANVISA) and FDA Quality System Regulation (21 CFR Part 820)

MDSAP Audit Process

- Why not just perform an audit to ISO 13485:2016?
  - There are specific requirements for each MDSAP participating regulatory authority
    - Medical device adverse event reporting
    - Advisory notice reporting
    - Device marketing authorization
    - Facility registration

MDSAP Audit Process

- Audit tasks within an MDSAP audit process
  - Are flexible
  - Are arranged in a logical order
  - May be performed in any order to facilitate a thorough and efficient audit of the process

MDSAP Audit Process

- Linkages and interactions between the MDSAP processes are indicated throughout the process (in the red box)
- Tasks involving risk management and risk based decisions are also indicated (in blue font)

MDSAP Audit Process

- The audit team will be asked to be mindful of “linkages”
- Quality management system has to identify and manage numerous interrelated (linked) processes
- The output of one process often directly forms the input of other processes
- The activities of a supporting process are relevant to other processes

MDSAP Audit Process

Linkages:

- Built into the MDSAP audit sequence and audit tasks
- Remind the audit team of the interactions between the processes
- Assist auditors in making appropriate selections when moving to the next process

MDSAP Audit Process

Risk Management:

- Assessed by the audit team during the audit
- An integral aspect of an organization's quality management system
- Top management provide the necessary commitment and resources for risk management activities

MDSAP Audit Process

- Effective risk management
  - Usually starts in conjunction with the design and development process
  - Proceeds through product realization, including the selection of suppliers
  - Continues until the time the product is decommissioned
- Risk-based decisions occur throughout the various quality management system processes
- Each organization must decide how much risk is acceptable

MDSAP Audit Process

- Guidance on assessing conformity is available in the MDSAP Audit Approach document
- Reference the MDSAP Audit Approach document as you complete the MDSAP training modules

Example 1 : MDSAP process

Auditing the Measurement, Analysis and Improvement Process

- Purpose:
  - Verify that the manufacturer's processes ensure that information related to products, processes, or the quality management system is collected and analyzed
  - Identify actual and potential product, process, or quality management system nonconformities
  - Ensure that problems and potential problems are investigated
  - Ensure that appropriate and effective corrective actions and preventive actions are taken

Example 1: MDSAP Process

Auditing the Measurement, Analysis and Improvement Process

- Outcomes: objective evidence that demonstrate whether the organization has:
  A. Defined, documented, and implemented procedures for measurement, analysis and improvement
  B. Identified, analyzed, and monitored appropriate sources of quality data and determined the need for corrective or preventive action

Example 1: MDSAP Process

Auditing the Measurement, Analysis and Improvement Process

- Outcomes: objective evidence will demonstrate whether the organization has:
  - C. Ensured investigations are conducted to identify the underlying causes of nonconformities and potential nonconformities, where possible
  - D. Implemented appropriate corrective action or preventive action

Example 1: MDSAP Process

Auditing the Measurement, Analysis and Improvement Process

- Outcomes: objective evidence will demonstrate whether the organization has:

E. Reviewed the effectiveness of corrective action and preventive action,

F. Utilized information from the analysis of production and post-production quality data to amend the analysis of product risk, as appropriate

Example 1: MDSAP Process

- Linkages to other MDSAP processes:
  - Design and Development process
  - Production and Service Controls
  - Purchasing
  - Medical Device Adverse events and Advisory Notice Reporting
  - Management

Example 1: MDSAP Process

Audit task

7. **When a corrective or preventive action results in a process change, confirm that the process change is assessed to determine if any new risks to the product are introduces.** Verify the manufacturer has performed revalidation of processes where appropriate.

Clause and regulation:[ISO 13485: 2016; 4.1.2, 4.1.4, 4.1.6, 4.2.1, 7.1, 7.5.2, 7.5.6, 7.5.7; TG(MD)R Sch1 P1 2; Sch3 P1 1.5(4); RDC ANVIS 16/2013: 2.4, 5.6, 7.1.1.4; MHLW MO169: 5, 6, 26, 45, 46; 21 CFR 820.100(a)(4), 820.100(a)(5), 820.70(b), 820.75(c)]

Example 1: MDSAP Process

Audit Task 7.

- Additional country-specific requirements (see MDSAP Audit Approach):
  - Australia (TGA): [TG(MD)R Sch3 P1 1.5(2)]
  - Canada (HC): [CMDR 1, 34]
  - Japan (MHLW): [MHLW MO169: 29]

Example 1: MDSAP Process

Audit Task 7.

- Links:
  - Production and Service Controls and Purchasing processes
- The audit team considers:
  - Selecting changed production processes for evaluation during Production and Service Control audit
  - Selecting suppliers who performed changes to production processes for evaluation
  - Re-validation, when the organization makes a change to a validated process performed by a supplier
- If re- validation is required, confirm the results show the process meets the planned results

Example 1: MDSAP Process

- Managing the linkage
  - The Purchasing process may be reviewed in conjunction with:
    - The Measurement, Analysis and Improvement process
    - The Design and Development process, and
    - The Production and Service Controls process

Example 1: MDSAP Process

- Managing the linkage:
  - Consider if corrective or preventive action resulted in process change
  - Consider selecting those processes or suppliers to audit involving the process change that was made as a result of corrective or preventive actions

MDSAP Audit Process

- Sampling Records:
  - Judgement-based sampling
    - Flexible
    - Generally, fewer records sampled
  - Statistical sampling
    - Demonstrates conformity or nonconformity

MDSAP Audit Process

- Sampling Records:
  - Judgement-based sampling
    - Often the most-appropriate sampling methods to achieve the MDSAP audit outcomes
    - Takes into account:
      - Complexity and interaction of the organization's processes and quality management system elements
      - Key risk areas

MDSAP Audit Process

- Sampling Records
  - Statistical sampling
    - May be appropriate in cases where no high risk nonconformities have been identified.
    - Helpful in making a statistical estimate of the effect of uncertainty in the findings of the audit and the conclusions reached
    - The level of sampling risk needs to be assessed by the auditor

MDSAP Audit Process

- Sampling products and processes
  - Assess all product families and significant processes during audit cycle
  - Degree of assessment depends on:
    - Risk of the product and process
    - Whether significant nonconformities can be attributed to the product or process
    - Whether any significant changes have been made to the products or processes

MDSAP Audit Process

- Design and implementation of an organization's quality management system is based on:
  - The needs of the organization
  - The size of the organization
  - The processes employed
  - The products provided
- If the organization does not perform certain processes, then:
  - The organization's quality management system does not need to address such a requirement
  - The corresponding MDSAP process does not need to be audited

MDSAP Audit Process

- Outsourcing
  - Much more common in the area of device design and manufacturing
  - Organizations can choose to outsource any processes related to the design and/or manufacture of medical devices
    - The suppliers of the processes **must** be controlled within the organization's quality management system
    - The supplied processes **must** be controlled within the organization's quality management system
  - Organizations cannot outsource responsibility for the device

MDSAP Audit Process

- Exclusions and Non-applicability
  - The organization may exclude the requirements of markets where the organization does not intend to supply product
  - The audit scope and audit criteria must take into account any justified exclusions or non-applications
  - Some MDSAP requirements may not be applicable when an organization claims an exclusion from the requirements of a target market
  - Exclusions must be clearly identified in the audit report

Learning Objectives

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- Describe the MDSAP Audit process and provide examples
- **Review requirements for writing nonconformity statements and the final report**

Nonconformity Statements

- During the audit, auditors must be mindful:
  - Of any instances where the organization demonstrates failure to fulfill any of the requirements in ISO 13485:2016
  - Of any instances where the organization demonstrates failure to fulfill any portion of the requirements listed in the audit activities and tasks
  - That these nonconformities are recorded in appropriate detail

Nonconformity Statements

- Pay attention to the potential interrelationship of the nonconformities observed
  - For example:
    - Audit findings in both purchasing controls and acceptance activities
    - May indicate a significant nonconformity because control over suppliers, and the products they supply, depends on an effective combination of both these activities
    - Deficiencies in one or the other may affect the quality of the finished device

Nonconformity Statements

- Generating audit findings
  - Nonconformities should be:
    - Recorded along with supporting evidence
    - Reviewed with the auditee
  - Nonconformities should include
    - A reference number or identifier
    - The date
    - Identification of the organization
    - Grading
    - The requirement that is not met
    - Supporting audit evidence
    - The name of the auditor issuing the nonconformity

Nonconformity Statements

- Nonconformities regarding country-specific requirements
  - Written as an audit finding
  - Documented in the audit report
- Exceptions to nonconformities regarding country-specific requirements
  - Exclusions and non-applications permitted by ISO13485:2016
  - Requirements of markets where the organization does not intend to supply product

Nonconformity Statements

- Document in the audit report:
  - Any observations related to device safety
  - Any observations related to the organization's
    - Failure to report individual adverse events
    - Advisory notices
    - Changes to device marketing authorization
    - Changes to facility registration

Final Report

- Report Format
  - Reports must be in the format described in the MDSAP AU P0019: Medical Device Regulatory Audit Reports Policy
  - Use the Fillable MDSAP Audit Report Form

References

- Medical device- Quality management systems- Requirements for regulatory purposes (ISO 13485:2016)
- Guidelines for auditing management systems (ISO 19011:2011)
- Conformity assessment-Requirements for bodies providing audit and certification of management systems (IS0/IEC 17021:2015)

References

- MDSAP AU P0002.5: MDSAP Audit Approach
- MDSAP AU P0008: Audit Time Determination Procedure
- MDSAP AU F0008.2: Audit Duration Calculation Form (Audit Model 2017)
- MDSAP AU P0019: Medical Device Regulatory Audit Reports Policy
- MDSAP AU F0019.1: Medical Device Regulatory Audit Report
- MDSAP AU F0019.2: NC Grading and Exchange Form
- MDSAP AU P0019.3: Medical Device Regulatory Audit Report Form Guidelines
- MDSAP AU G0019.4: NC Grading Exchange Form Guidelines

References

- Australia (TGA)
  - Therapeutic Goods Act 1989
  - Therapeutic Goods (Medical Devices) Regulations 2002
  - Uniform Recall Procedure for Therapeutic Goods (URPTG)
- Brazil (ANVISA)
  - Brazilian Good Manufacturing Practices (RDC ANVISA 16/2013)

References

- Health Canada (HC)
  - Medical Devices Regulations (SOR/98-282)
- Japan
  - Japan Ordinance on Standards for Manufacturing Control and Quality Control of Medical Devices and In Vitro Diagnostic Reagents (MHLW Ministerial Ordinance No. 169)
  - The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics (Law No. 145, 1960)

References

- United States (FDA)
  - Labeling (21 CFR 801)
  - Quality System Regulation (21 CFR 820)
  - Medical Device Reporting (21 CFR 803)
  - Medical Devices: Reports of Corrections and Removals (21 CFR 806)
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Conclusion

- There are prerequisites for an MDSAP Auditor
- The MDSAP Audit process includes:
  - A purpose
  - Expected Outcomes
  - Audit tasks
  - Final Report
- Nonconformities should be documented in the Final Report using the fillable MDSAP Audit Report Form

Conclusion

This concludes the Overview of the MDSAP Audit Process training module.


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